rently employed and identify opportunities for future research. **METHODS:** A comprehensive literature review of reference databases, conference abstracts, journals and medical societies' websites was performed. Publications reporting practice management efficiency measures within ambulatory oncology practices and infusion centers located in the United States were included. Search was limited to English-language articles published between 2007 and 2010. All publication types except continuing medical education materials and letters to the editor were accepted. Evidence quality was assessed with the Completeness of Reporting index (CORE-14) instrument. **RESULTS:** Forty-seven references were accepted for inclusion. Efficiency strategies were classified into 7 distinct categories, each reported at a similar frequency in the literature. Within and across these categories, common themes were standardization of care, use of best practices, and alignment between quality and profitability initiatives. Most publications were recommendations without a study design type (64%) and/or did not report quantifiable outcome data (74%). Additionally, 21 publications did not define the practice type included, while the remaining articles identified 12 different practice types. Consequently, applicability is limited, since outcomes cannot be associated with a particular practice type. Thirty-four publications were assigned a CORE-14 score of 0, indicating they did not meet any criteria for methodological quality (mean score, 1.84). **CONCLUSIONS:** Numerous efficiency methods are being touted in the literature, but there is limited definitive data on the successfulness of these techniques. Further research, of a high methodological caliber, is needed to support informed decisions. Specifically, registries, surveys, and economic analyses would empower oncologists and other oncology professionals with practical strategies to concurrently improve quality while maintaining profitability.

PCN138

A REVIEW OF EXPANDED ACCESS PROGRAMS (EAP) AND THEIR CONSIDERATION BY HEALTH PLAN DECISION-MAKERS IN THE UNITED STATES

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OBJECTIVES: After failing approved treatments, patients may receive investigational therapies through participation in a clinical trial or an expanded access program (EAP). EAPs were established after the FDA decided to allow patients access to investigational drugs for treatment purposes, and since then EAPs have been set up in various therapeutic areas including oncology and infectious diseases. No analysis, however, has been completed evaluating the use and value of EAP data to US payers. **METHODS:** We analyzed the impact of EAP data on the US payer decision making process in drug formulary positioning. Using examples of different types of drug data including EAP, payers were asked how each type affected drug coverage. After reviewing these results, we assessed payers' awareness of EAP relative to other data types to determine future impacts of EAP. Our study allowed us to define the key value drivers for EAP trials and construct a value matrix to evaluate future EAP opportunities. **RESULTS:** Payers in the United States had a low awareness of EAP data driven by a lack of exposure to the data type but mostly attributed to their sole use of RCT data in formulary decisions. While most payers agreed that EAP data has little influence on their decision making process, they did highlight factors that make EAP data more valuable to other stakeholders and discussed how EAP data could improve product perception. **CONCLUSIONS:** Our findings suggest that payers will not change their management approach and formulary decisions based on EAP data. Payers realize that EAP data might be more representative of the real world patient population than data from RCTs; however, RCTs will remain the gold standard data source to evaluate agents for reimbursement and formulary placement.

Gastrointestinal Disorders – Clinical Outcomes Studies

PGI1

INCIDENCE OF ANEMIA AND NEUTROPENIA FOLLOWING HCV TREATMENT INITIATION AND RELATED DRUG TREATMENT COSTS IN THE UNITED STATES

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OBJECTIVES: Conventional peginterferon-ribavirin antiviral treatment of chronic hepatitis C virus (HCV) often leads to anemia and neutropenia. Based on US claims data, we explored the incidence of both adverse events (AEs) and the associated risk factors, and assessed the related erythropoietin/granulocyte colony stimulating factor (G-CSF) costs in daily clinical practice. **METHODS:** Commercially insured patients with chronic HCV infection (ICD9 070.44,070.54,070.70,070.71) (all genotypes), who initiated any combination of (peg)interferon and/or ribavirin were identified in a large US claims database (Thomson 2006–2009). Time to first onset of anemia and neutropenia was analyzed using Kaplan-Meier and Cox proportional hazards regression. Anemia and neutropenia were defined based on ICD9-coding (280-285,288) and/or prescription of erythropoietin and G-CSF. **RESULTS:** 3,935 chronic HCV-infected patients (mean age 51.1, 63% male) initiated HCV treatment. 86% of the patients initiated a combination of peginterferon and ribavirin. Mean treatment duration was 245 days. Regardless of time on treatment, 32%/17% of the cohort experienced anemia/neutropenia respectively. Age, female gender, Charlson co-morbidity index and liver cirrhosis were predictive for both AEs. 20.3%/11.3% of the cohort received erythropoietin/G-CSF treatment respectively, on average for 131/126 days. The mean cost for the entire cohort to manage both AEs was $2,263 (erythropoietin) and $1,004 (G-CSF), which represents 12% of the overall healthcare cost in the follow-up year for the entire cohort. The majority of the costs associated with AE-related treatments (58%/54%) occurred after week 24 of therapy. **CONCLUSIONS:** Costs of managing anemia and neutropenia during HCV treatment are considerable and often continued beyond 24 weeks of treatment. New HCV treatment combinations allowing to shorten treatment up to 24 weeks, may considerably reduce AE-related costs. This reduction may be most important in treatment-naive genotype 1-infected patients, as the standard 48-week treatment duration is longer compared with other genotypes.

PGI2

PREDICTORS OF PROTON PUMP INHIBITOR (PPI) DOSING REGIMEN AMONG PATIENTS WITH GASTROESOPHAGEAL REFLUX DISEASE (GERD)

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OBJECTIVES: The aim of this study was to explore the predictors of PPI dosing regimen [once daily (QD) or twice daily (BID)] among patients with GERD. **METHODS:** Using the HealthCore Integrated Research Database from 01/01/2004-06/30/2009, GERD patients (ICD-9 codes 530.10-530.13, 530.19, 530.81, or 787.1x), ≥ 18 years of age, having at least two PPI pharmacy claims (index date) from 01/01/2005-06/30/2008 and continuous eligibility for 12 months before and after the index date were identified. Based on the PPI dosing regimen throughout the post-index period, calculated as the ratio of quantity of medication dispensed/number of days supply, GERD patients were classified as QD (ratio of < 1.5) or BID (ratio of ≥ 1.5) PPI users. Descriptive analyses were used to compare QD vs. BID PPI users and a multivariate logistic regression was conducted to assess independent predictors of BID PPI use. **RESULTS:** This study included 248,386 GERD patients with a mean age of 52.8 (+13.93) years and 56% were females. Based on the dosing regimen, 90% (n=222,759) were classified as QD and 10% (n=25,627) as BID PPI users. Patients with BID PPI dosing were significantly (all $p<0.0001$) more likely to have Barrett's Esophagus (5% vs. 2%), baseline H2RA use (8.7% vs. 6.8%) and higher comorbidity based on mean Deyo Charlson's Comorbidity Index score (DCI) [0.89 (SD=1.54) vs. 0.70 (SD=1.37)]. Logistic regression results demonstrated that females [OR=1.13 (95% CI=1.08-1.18)], a diagnosis for Barrett's Esophagus [OR=2.08 (95% CI=1.84-2.36)], baseline H2RA [OR=1.29 (95% CI=1.20-1.39)] or PPI use [OR=1.67 (95% CI=1.59-1.74)] and higher DCI score [OR=1.09 (95%CI=1.08-1.10)] were significant (all $p<0.0001$) predictors of BID PPI use. **CONCLUSIONS:** Patients who have a diagnosis of Barrett's Esophagus, had baseline use of PPI or H2RA therapy were found to be significant predictors of BID PPI dosing. Further studies understanding the differences in clinical and economic outcomes based on PPI dosing regimen should be undertaken.

PGI3

THE LIKELIHOOD OF HAVING FUNCTIONAL DYSPEPSIA BASED ON OTHER COMORBID CONDITIONS

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OBJECTIVES: The etiology of functional dyspepsia (FD) is debated. However, limited published data exist on the associated co-morbid conditions with FD. This study aimed to assess the odds (likelihood) of having FD based on the presence of other objectively defined comorbid conditions. **METHODS:** Retrospective database analysis on a 4-year study period (2001-2004), using payroll data and adjudicated health insurance medical and prescription claims on more than 300,000 employees. Study comparisons were performed among employees with FD (ICD9= 536.8x) and propensity-score-matched employees without FD (controls, matched on age, gender, tenure with employer, marital status, race, region, salary, exempt status, and full-time/part-time). Comorbid conditions were Specific Conditions (SC) defined by the Agency for Healthcare Research and Quality (AHRQ). Subjects were classified as having the condition by any claims with an ICD-9 code for the SC. The likelihood of being in the FD cohort was modeled using logistic regression with indicator (1/0) variables for 260 of the 261 specific AHRQ SCs (the FD-SC was not included). Odds ratios >1.0 indicate the corresponding SC is more likely in the FD cohort, while ratios <1.0 indicate the SC is less likely to be in the FD cohort. **RESULTS:** The study dataset contained 85,119 employees (1669 with FD and 83,450 matched controls without FD). After controlling for all other AHRQ categories, the logistic regression found that 19 specific categories were more likely within the FD cohort, and 2 were less likely within the FD cohort. Esophageal disorders, gastritis and duodenitis, abdominal pain, and gout were most associated with having FD (odds ratios of 3.8, 3.7, 3.6, and 2.5, respectively). Only hypertension complications/secondary and disorders of teeth and jaw were significantly negatively associated with FD. **CONCLUSIONS:** This study identified varied comorbidities associated with FD diagnoses and may aid FD identification in future research.

PGI4

PREDICTORS OF HEPATITIS C TREATMENT INITIATION

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OBJECTIVES: Chronic hepatitis C, in its early stages, is commonly asymptomatic, and many patients do not seek treatment. The current study attempts to identify the characteristics of hepatitis C patients who initiate treatment for hepatitis C. **METHODS:** This study is based on data from the 2009 and 2010 waves of the US National Health and Wellness Survey (N=132,478), a cross-sectional database representative of the adult US population. Patients who reported having been diagnosed with hepatitis C by a physician were included for analysis (n=1279). Patients currently, or ever, taking a prescription medication for hepatitis C (n=579) were compared with patients who never took a prescription for hepatitis C (n=700). Group membership was predicted with a logistic regression model, including age,